143

(4)

No. 09-198

Supreme Court, U.S.
FILED
OCT 16 2009
OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

MEDELA AG AND MEDELA, INC.,
Petitioners,

v.

KINETIC CONCEPTS, INC., ET AL.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

Of Counsel

R. LAURENCE MACON
KAREN KROESCHE GULDE
AKIN GUMP STRAUSS
HAUER & FELD LLP
300 Convent Street
San Antonio, TX 78205
(210) 281-7000

DONALD R. DUNNER
Counsel of Record
DON O. BURLEY
ERIK R. PUKNYS
TINA E. HULSE
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4000

Attorneys for Respondents

October 16, 2009

QUESTION PRESENTED

The ultimate judgment of obviousness is a legal issue, but it is well recognized that any underlying factual issues are for the jury. Here, Medela consented to having the jury render a general verdict on obviousness—and did not ask for special interrogatories on any underlying factual issue—and the jury rejected Medela's obviousness claim. On appeal, the Federal Circuit, consistent with this Court's precedent, presumed that the jury had resolved the factual issues underlying obviousness in KCI's favor, applied the substantial-evidence standard of review, and determined that the verdict of nonobviousness was legally correct.

The question presented is:

Whether, where the parties have *consented* to giving the issue of obviousness to the jury, it is error for the appellate court to assess the jury's verdict by presuming that the jury made factual findings in the prevailing party's favor, applying the substantial-evidence test, and examining legal questions on a de novo basis.

RULE 29.6 STATEMENT

All parent corporations and any publicly held companies that own 10 percent or more of Respondents' stock are:

Kinetic Concepts, Inc., a publicly traded company, is the parent corporation of both KCI Licensing, Inc., and KCI USA, Inc.

Invesco PLC, which owns the AIM and Invesco families of mutual funds, owns 10% or more of Kinetic Concepts, Inc., either directly or through its mutual funds.

Wake Forest University is the parent of Wake Forest University Health Sciences.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

RULE 29.6 STATEMENT ii

TABLE OF AUTHORITIES v

I. PRELIMINARY STATEMENT 1

II. FACTUAL BACKGROUND 4

A. The Invention 4

B. The District Court Proceedings 4

C. The Federal Circuit's Decision 9

D. Post-Trial PTO Proceedings Regarding the Patents-in-Suit 12

III. ARGUMENT 13

A. Medela Never Objected to the Jury's Role in the District Court 13

B. The Federal Circuit Properly Reviews Jury Verdicts on Obviousness, and Did So Here 16

C. The Federal Circuit Recognized the Proper Roles of the Jury (Finding the Facts) and the Court (Determining the Law) 19

1. The "Circuit Split" Is, At Most, Wholly Theoretical 19

2. The Federal Circuit's Approach Was Consistent with This Court's Precedent 26

D. Medela's Argument that the Jury Should Have *No* Role in Deciding Obviousness Goes Too Far 28

CONCLUSION 35

TABLE OF AUTHORITIES

CASES

Agrizap, Inc. v. Woodstream Corp.,
520 F.3d 1337 (Fed. Cir. 2008) 17

American Airlines, Inc. v. Lockwood,
515 U.S. 1121 (1995) 33

Anderson's-Black Rock, Inc. v. Pavement Salvage Co.,
396 U.S. 57 (1969) 27

Arsement v. Spinnaker Exploration Co.,
400 F.3d 238 (5th Cir. 2005) 12

Baumstimler v. Rankin,
677 F.2d 1061 (5th Cir. 1982) 25, 26

Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,
489 U.S. 141 (1989) 20

Boston Scientific Scimed, Inc. v. Cordis Corp.,
554 F.3d 982 (Fed. Cir. 2009),
petition for cert. dismissed, No. 09-103,
2009 U.S. LEXIS 7156 (Oct. 2, 2009) 18

Chesapeake Insurance Co. v. Stark,
10 U.S. (6 Cranch) 268 (1810) 31

Control Components, Inc. v. Valtek, Inc.,
609 F.2d 763 (5th Cir. 1980) 24

Cooley v. O'Connor,
79 U.S. (12 Wall.) 391 (1870) 31

Dann v. Johnston,
425 U.S. 219 (1976) 27

Davis & Cox v. Summa Corp.,
751 F.2d 1507 (9th Cir. 1985) 32

Graham v. John Deere Co.,
383 U.S. 1 (1966) 6, 7, 26, 29

Hogg v. Emerson,
52 U.S. (11 How.) 587 (1850) 30

Hotchkiss v. Greenwood,
52 U.S. (11 How.) 248 (1851) 29

In re GPAC, Inc.,
57 F.3d 1573 (Fed. Cir. 1995) 7

In re Japanese Electronic Products Antitrust Litigation,
631 F.2d 1069 (3d Cir. 1980) 33

In re Lockwood,
50 F.3d 966 (Fed. Cir. 1995) 34

In re U.S. Financial Securities Litigation,
609 F.2d 411 (9th Cir. 1979) 32

Jurgens v. McKasy,
927 F 2d 1552 (Fed. Cir. 1991) 16

Kerman v. City of New York,
374 F.3d 93 (2d Cir. 2004) 15

Kim v. ConAgra Foods, Inc.,
465 F.3d 1312 (Fed. Cir. 2006) 7

KSR International Co. v. Teleflex Inc.,
550 U.S. 398 (2007) 16, 27

LNP Engineering Plastics, Inc. v. Miller Waste Mills, Inc.,
275 F.3d 1347 (Fed. Cir. 2001) 11

Machine Co. v. Murphy,
97 U.S. 120 (1877) 31

Manchester v. Ericsson,
105 U.S. 347 (1881) 31

McDermott International, Inc. v. Wilander,
498 U.S. 337 (1991) 30

McGinley v. Franklin Sports, Inc.,
262 F.3d 1339 (Fed. Cir. 2001) 14

Panther Pumps & Equipment Co. v. Hydrocraft, Inc.,
468 F.2d 225 (7th Cir. 1972) 23

Perkin-Elmer Corp. v. Computervision Corp.,
732 F.2d 888 (Fed. Cir. 1984) 14, 20, 21

PharmaStem Therapeutics, Inc. v. ViaCell, Inc.,
491 F.3d 1342 (Fed. Cir. 2007) 17, 27

Reeves v. Sanderson Plumbing Products, Inc.,
530 U.S. 133 (2000) 19

Republican River Bridge Co. v. Kansas Pacific Railway Co.,
92 U.S. 315 (1875) 31

Roberts v. Sears, Roebuck & Co.,
723 F.2d 1324 (7th Cir. 1983)
(en banc) 22, 24, 29

Sakraida v. Ag Pro, Inc.,
425 U.S. 273 (1976) 27

Sarkisian v. Winn-Proof Corp.,
688 F.2d 647 (9th Cir. 1982) (en banc)
(per curiam) 20, 29

Tucker v. Spalding,
80 U.S. (13 Wall.) 453 (1872) 29

TypeRight Keyboard Corp. v. Microsoft Corp.,
374 F.3d 1151 (Fed. Cir. 2004) 7

United States v. Adams,
383 U.S. 39 (1966) 27

United States v. Torniero,
735 F.2d 725 (2d Cir. 1984) 33

I. PRELIMINARY STATEMENT

At its essence, Medela's[1] certiorari petition challenges the Federal Circuit's refusal to find error in the district court's decision not to substitute its fact-finding for the jury's on the issue of obviousness. But the procedures followed in the district court—including the submission of the obviousness issue to the jury with no special interrogatories—were all *with Medela's consent.* And both the district court and the Federal Circuit followed well-established law in upholding the jury's verdict that the asserted claims were nonobvious.

Following a six-week trial, the jury was instructed on Medela's obviousness defense and asked to reach a general verdict on obviousness. But rather than objecting to this procedure—as one might assume were the case from reading Medela's certiorari petition—Medela fully consented to it. Indeed, while the Federal Circuit has *encouraged* parties in Medela's position to ask for special interrogatories relating to the facts underlying a verdict on an issue such as obviousness, Medela never did that. Instead, Medela was perfectly happy entrusting the obviousness issue to the jury—until it

---

[1] "Medela" is used to refer collectively to Petitioners Medela AG and Medela, Inc. The action below was also brought against Blue Sky Medical Group, Inc. ("Blue Sky"), but neither Blue Sky nor its subsequent acquirer, Smith & Nephew, Inc., is a party to Medela's certiorari petition.

returned its verdict that the asserted claims were nonobvious.

After the district court denied Medela's renewed motion for judgment as a matter of law ("JMOL"), Medela appealed and the Federal Circuit affirmed. Following this Court's precedent, the Federal Circuit thoroughly reviewed the evidence, drawing all reasonable inferences in KCI's[2] favor, and found that substantial evidence supported the jury's verdict.

Not liking that result, Medela has now come to this Court, asserting that "[u]nder Federal Circuit precedent . . . , a person accused of patent infringement has no right to independent judicial, as distinct from lay jury, determination of obviousness." Medela Pet. for Writ of Cert. ("Pet.") at i. The crux of Medela's argument is that under Federal Circuit precedent, a jury that returns a verdict on the issue of obviousness does not provide any explanation of its verdict, which makes it impossible for the court to know the underlying rationale of the jury's verdict. Thus, Medela complains that in this case, the Federal Circuit had to "assume" that the jury resolved the facts in KCI's favor, since the jury's actual findings would be "impossible to know or to determine." *Id.* at 9.

---

[2] "KCI" is used to refer collectively to Respondents Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences.

But the premise of Medela's argument is wrong. Under Federal Circuit precedent, a party accused of infringement (or the patentee, for that matter) can request a jury verdict form with interrogatories directed to the factual findings the jury is required to make. In fact, far from forbidding this practice (as Medela suggests), the Federal Circuit has *encouraged* parties to request the submission of factual interrogatories to the jury precisely to facilitate the review of the verdict. Here, however, Medela's counsel never asked the district court to submit special interrogatories to the jury.

Medela also mischaracterizes what happens when parties request a general verdict from the jury, whether regarding obviousness or any other issue that is ultimately a question of law based on underlying facts. In that situation, the reviewing court has no choice but to assume the jury resolved the underlying factual issues in the prevailing party's favor, and its review can only look to whether the presumed factual findings are supported by substantial evidence. To review the jury's verdict in any other way would usurp the jury's constitutional fact-finding role.

KCI respectfully requests that the Court deny Medela's petition for a writ of certiorari.

II. FACTUAL BACKGROUND

A. The Invention

The invention covered by the patents-in-suit is a "negative pressure wound therapy" ("NPWT") system. The invention is often used to treat chronic wounds, which are wounds that do not heal and stay open for weeks, months, and sometimes even years. Before the invention, patients with chronic wounds had few treatment options, all of which were both painful and largely ineffective, frequently ending in amputation. But the NPWT system invented by Drs. Louis Argenta and Michael Morykwas—colleagues at Wake Forest University School of Medicine—changed wound-care treatment forever.

Despite initial skepticism from their peers, the inventors tested their device on patients with severe chronic wounds. To everyone's surprise, the wounds healed. Today, the invention's commercial embodiment—the V.A.C.® therapy system ("VAC") sold by KCI—has been used to treat more than a million patients and is used in virtually every major medical center in the developed world. In 2006, a nationwide group of senior plastic surgeons recognized the VAC as the biggest advance in their field in the preceding decade.

B. The District Court Proceedings

After Blue Sky released an NPWT product, KCI brought a patent-infringement suit against both Blue Sky and its vacuum-pump supplier, Medela. At

trial, Blue Sky and Medela raised numerous defenses, including obviousness over various prior-art techniques, most of which had already been considered by the PTO before issuing the patents-in-suit.

During the six-week trial, the parties presented competing expert testimony regarding validity. KCI's expert testified that each prior-art technique lacked at least one limitation of each asserted claim. For example, the key contested limitation found in all of the claims was "treating a wound with negative pressure," and this limitation served as the focal point of the parties' trial presentations.

KCI's expert, for instance, explained in detail why the prior art that defendants relied on lacked this limitation. Among other things, he testified that Medela's two main prior-art techniques, described in references authored by Chariker-Jeter and Davydov, disclosed systems that drained, respectively, a fistula (i.e., a hole between two organs such as the skin and the intestines) and a pocket of pus inside the breast. Because neither a fistula nor a "pus pocket" is a "wound" within the meaning of the asserted patents, KCI's expert concluded that neither reference disclosed "treating a wound." KCI's expert also explained why the other prior-art references, Svedman and Johnson, did not render the asserted claims obvious. As he testified, Svedman taught treating a wound with an irrigation device, and Johnson taught treating a wound with a

skin graft. Thus, KCI's expert concluded that neither reference taught "treating a wound *with negative pressure*." KCI also presented extensive testimony supporting secondary considerations of nonobviousness, including initial skepticism, unexpected results, long-felt need, commercial success, peer recognition, and copying.

The court's instructions to the jury included over seven pages devoted to the obviousness issue. The instructions thoroughly explained the factors that the jury was to consider and the potential pitfalls to avoid in determining obviousness. For example, the instructions taught that:

> The issue is not whether the claimed invention would have been obvious to you, to me as a judge, or to a genius in the field of the invention. Rather the question is whether or not the invention would have been obvious to a person of ordinary skill in the field of the invention.

The instructions further explained that the jury "must avoid using hindsight," and must "not use the patents as a road map for selecting and combining items of prior art."

Next, the instructions focused on the four *Graham* factors (from *Graham v. John Deere Co.*, 383 U.S. 1 (1966)) and explained what facts the jury had to find for it to find the asserted claims obvious or nonobvious. And regarding the objective

indications concerning obviousness, the instructions indicated that the jury "must consider certain factors, which, if established, weigh in favor of finding that the invention would not have been obvious," but that "[n]o factor alone is dispositive."[3]

But while one might infer from Medela's discussion of the instructions on obviousness (*see* Pet. 5-6) that Medela objected to them, or at least *some* of them, that would be wrong. At no point during the trial did Medela ever object to the instructions on obviousness. In fact, at the Federal Circuit, Medela readily admitted that it *stipulated* to the instructions. Br. of Appellants, Medela AG and

---

[3] Medela asserts that the jury's determinations of the *Graham* factors were "dependent on various subsidiary legal conclusions." Pet. 5-6. But the *Graham* factors are "basic factual inquiries," and each of the eight alleged "subsidiary legal conclusions" listed by Medela is either solely or principally an issue of fact. *See, e.g., Graham*, 383 U.S. at 17 (stating that the obviousness determination "lends itself to several basic factual inquiries" and then identifying the inquiries, now called the four *Graham* factors); *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1326 (Fed. Cir. 2006) ("The determination of what a prior art reference discloses is a question of fact."); *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004) (stating that whether a reference is prior art "is a question of law based on underlying fact questions"); *In re GPAC, Inc.*, 57 F.3d 1573, 1577 (Fed. Cir. 1995) (stating that in determining the scope and content of the prior art, "whether a reference . . . is 'analogous' is a fact question"); *id.* at 1579-80 (reviewing the factors for determining the level of ordinary skill in the art as factual findings).

Medela, Inc. ("Medela CAFC Br.") 55 (admitting that "the parties stipulated to the jury instructions on obviousness"). Nor did Medela object to the general verdict form that asked the jury to answer "yes" or "no" to whether the asserted claims were obvious. Moreover, Medela never objected to the jury deciding the ultimate question of obviousness, Medela never suggested that the jury's verdict should be considered "advisory" only, and Medela never sought special interrogatories in which the jury would have answered specific questions relating to the factual issues underlying obviousness. Thus, despite its current complaints, at trial, Medela *consented* to the jury's role in determining obviousness.

After deliberating, the jury returned the general verdict form, answering "no" to whether defendants proved each of the claims was obvious. As Medela notes, "[t]he jury was not asked to provide, and did not provide, any explanation of these 'no' answers." Pet. 6-7. But what Medela ignores is that it never suggested that the jury *should* provide any explanation for its answers.

Medela then filed a renewed JMOL motion on the issue of obviousness, which the district court denied. The court first noted the "difficult burden" that Medela had to meet to show that no reasonable jury could have decided that Medela failed to meet its clear and convincing burden. Appendices to Pet. ("App.") 50a. Based on the extensive evidence and testimony presented by both sides, the court found that substantial evidence supported the jury's

verdict. The court properly held that "[i]t is the province of the jury—not the judge—to determine the credibility of witnesses." *Id.* at 58a. In considering the evidence, the court also noted that "while it may be true that Defendant Medela provided arguably ample evidence of patent invalidity, such evidence carries only the weight as measured by a pool of dedicated jurors." *Id.* at 58a-59a. Thus, the court considered all of the evidence presented at trial and, while appropriately deferring to the factual findings of the jury, determined that substantial evidence supported the jury's verdict. *Id.* at 58a (stating that in "[a]pplying the legal standards and upon review of the briefing, the Court finds sufficient evidence to justify the jury's verdict").

C. The Federal Circuit's Decision

On appeal to the Federal Circuit, one of Medela's arguments was that the district court had erred in denying its JMOL motion that the asserted claims were invalid as obvious.[4]

In its opinion, the Federal Circuit first considered the claim term "wound," the construction

---

[4] Alternatively, Medela sought a new trial on obviousness, and Medela also challenged the district court's decision rejecting its argument that certain claim terms were invalid as indefinite. However, Medela did not challenge the district court's decision (based on the jury's verdict) that the asserted claims were not invalid as anticipated.

of which was relevant to the obviousness inquiry. Medela asserted that the term "wound" should be broadly construed (according to a medical dictionary) to encompass both traumas to any body tissue and surgical incisions. App. 13a. KCI, on the other hand, asserted that because every example in the specification describes skin wounds, the correct construction of "wound" is "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." *Id.* at 14a.

The Federal Circuit agreed with KCI that the specification did not support Medela's overly broad construction of "wound." Recognizing that the parties' dispute affected only two of the prior-art techniques—Chariker-Jeter and Davydov—the court stated that:

> We agree with KCI that "wound," as used in the asserted patents, does not cover the fistulae described in the Chariker-Jeter publications and the "pus pockets" described in the Davydov references. . . . All of the examples described in the specification involve skin wounds. To construe "wound" to include fistulae and "pus pockets" would thus expand the scope of the claims far beyond anything described in the specification.

Id. at 15a (citation omitted).

Turning from claim construction to the obviousness issue, and whether substantial evidence supported the jury's verdict of nonobviousness, the Federal Circuit first recognized that because the scope and content of the prior art were "factual issues to be determined by the jury," the court was required to "review[] these factual determinations, 'whether explicit or implicit within the verdict, for substantial evidence.'" *Id.* at 17a (quoting *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001)).

The court then discussed Medela's position that the prior art—specifically, Chariker-Jeter, Davydov, Svedman, and Johnson—disclosed "treating wounds with negative pressure" (App. 16a-17a) and identified the substantial evidence that KCI had presented to show that none of the prior art Medela relied on disclosed treating wounds with negative pressure in the manner of the claimed invention (*id.* at 17a-19a). Thus, the court concluded that "KCI addressed each of Defendants' prior art references and provided the jury with a basis for determining that they did not teach or suggest 'treating a wound with negative pressure,' a limitation found in every asserted claim." *Id.* at 19a.

The Federal Circuit also addressed Medela's argument that the district court erred by failing to conduct its own obviousness analysis. But the court noted that Medela's "obviousness argument at trial relied heavily on the prior art references, the scope and content of which are factual questions to be

determined by the jury." *Id.* at 20a. Then, the court recognized that "KCI presented substantial evidence to support its interpretation of the references," and that its obligation under Fifth Circuit case law was to view "the evidence, as well as all reasonable inferences from it," "in the light most favorable to the verdict." *Id.* (citing *Arsement v. Spinnaker Exploration Co.*, 400 F.3d 238, 249 (5th Cir. 2005)). Thus, the Federal Circuit held that it "must assume" that the jury resolved this factual dispute in KCI's favor and concluded that the prior art did not disclose the "treating a wound with negative pressure" limitation. *Id.*

D. Post-Trial PTO Proceedings Regarding the Patents-in-Suit

In its reply brief in the Federal Circuit, Medela stated that it was "noteworthy" that the patents-in-suit "now stand rejected in a reexamination proceeding based upon the Svedman Article." Reply Br. of Appellants, Medela AG and Medela, Inc. ("Medela CAFC Reply Br.") 33 n.6. Subsequently, however, the PTO issued a notice of intent to issue a reexamination certificate for the two patents-in-suit. Following the reexamination proceedings, twelve of the sixteen asserted claims of one asserted patent (U.S. Patent No. 5,636,643) remained unchanged[5] and all twenty-one of the

[5] During the reexaminations, the patentee (Wake Forest University Health Sciences) amended claim 38 of this patent and canceled claims 13-15.

asserted claims of the other asserted patent (U.S. Patent No. 5,645,081) remained unchanged.

III. ARGUMENT

A. Medela Never Objected to the Jury's Role in the District Court

While Medela challenges the Federal Circuit's decision to apply the substantial-evidence test to the jury's verdict of nonobviousness, asserting that it was entitled to an "independent judicial" determination of the issue, Medela has no grounds for complaint. The manner in which the jury's verdict was reviewed—indeed, in which it *had to be reviewed*—was the direct consequence of Medela's own decisions, including its decisions (1) to stipulate to the district court's instructions on obviousness, (2) to provide the jury with a general verdict form in which the jury could answer only "yes" or "no" on the obviousness issue, and (3) not to seek special interrogatories on the factual issues underlying obviousness. Given its *consent* to the procedures followed in the district court, Medela cannot now complain that because the jury answered only "no" on the obviousness issue, the Federal Circuit had to presume that the jury resolved the facts underlying the obviousness issue in KCI's favor. Medela is a sophisticated litigant that was represented by highly qualified counsel. Medela therefore understood the consequences of providing a general verdict form to the jury.

Indeed, for years, the Federal Circuit has strongly encouraged the use of special interrogatories to facilitate review of the jury's factual findings. In *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888 (Fed. Cir. 1984), for example, the jury returned a general verdict (with no objection from the parties) that the claims at issue were valid. As a result, the court noted that "the law presumes the existence of findings necessary to support the verdict the jury reached" (*id.* at 893), and it proceeded to determine whether substantial evidence supported the jury's verdict (*id.* at 893-94). But the Federal Circuit expressly stated that it would have *preferred* that the parties use special interrogatories:

> To facilitate review on a motion for JNOV and on appeal, it is preferred that a jury be provided with special interrogatories designed to reveal more clearly the findings it made.

Id. at 893; *see also* Br. for Apple, Inc., et al., as Amici Curiae Supporting Pet'rs 10-11 (discussing the Federal Circuit's preference for special interrogatories).

And in *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339 (Fed. Cir. 2001), the Federal Circuit noted that the parties' failure to use special interrogatories in the context of determining obviousness made it impossible for the court to determine which specific pieces of evidence the jury relied on in reaching its decision. *Id.* at 1356. Nonetheless, the court held

that the parties were free to use a general verdict if that is what they desired:

> Our law does not compel the use of special verdicts in these cases, and so long as the parties are content to give the jury unfettered room to operate on dispositive factual issues within the scope of a general verdict request, we must be mindful of our role as an appellate court and respect the verdict reached, notwithstanding what may seem to some to be an invention of little novelty.

Id.

Other circuits take a similar approach to litigants who consented to the jury being asked to render a general verdict regarding an issue that is ultimately one of law but has underlying factual issues. For example, *Kerman v. City of New York*, 374 F.3d 93 (2d Cir. 2004), involved the affirmative defense of qualified immunity, which, like obviousness, is a mixed question of law and fact. *Id.* at 109. The court held that, typically, the defendant must request special interrogatories on the key issues of fact, and the court must then decide the ultimate question of law. *Id.* at 119. But because the defendant failed to ask for specific interrogatories, the court held the defense was "effectively waived" because the court could not substitute its factual findings for the jury's. *Id.* at 118. As the court concluded, "it was incumbent on

[defendant] to request that the jury be asked the pertinent question. Not having made such a request, [defendant] was not entitled to have the court, in lieu of the jury, make the finding." *Id.* at 120.

B. The Federal Circuit Properly Reviews Jury Verdicts on Obviousness, and Did So Here

Medela claims that "Federal Circuit precedent broadly and improperly abrogates any right to independent judicial, as distinct from lay jury, determination" of obviousness. Pet. 9. But Federal Circuit precedent has long held that while the jury's underlying factual findings are given due deference, the ultimate question of obviousness is a question of law for the court to decide de novo—i.e., independently. *See, e.g., Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991) (explaining this two-part appellate review for issues of law, like obviousness, that are submitted to the jury upon disputed facts).

Moreover, the Federal Circuit's cases indicate that, in practice, the court has not abdicated its responsibility to determine the law, and that it has independently reviewed jury verdicts of nonobviousness—and overturned them where appropriate. Looking at Federal Circuit decisions post-dating this Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), for example, shows that in the following cases, the jury's nonobviousness verdict was reversed:

- *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007). In this case, the Federal Circuit began its review of the jury's obviousness verdict by noting that "[o]bviousness is a legal conclusion that we review de novo." *Id.* at 1359. The court also recognized that "[u]nderpinning that legal issue are factual questions relating to the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations, such as commercial success, long-felt need, and the failure of others." *Id.* Thus, the Federal Circuit stated that "in reviewing the denial of the JMOL motion on the issue of obviousness, we examine the evidence in the light most favorable to the verdict and determine whether a reasonable jury could have found all the facts necessary to support the verdict of nonobviousness, i.e., whether substantial evidence supports the verdict." *Id.* at 1360. The court then provided a multi-page analysis of both the prior art and the testimony presented at trial, including evidence of "secondary considerations," and reversed, concluding that a reasonable jury could not have found the invention nonobvious. *Id.* at 1360-67.

- *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008). Here, the jury returned a general verdict that the claims were not obvious and the district court denied the defendant's JMOL motion. In reviewing the judgment, the Federal Circuit noted the jury's role as fact finder and the "high level of deference" that it should thus be

accorded. *Id.* at 1342-43. Further, although the Federal Circuit presumed that all factual disputes were resolved in the patentee's favor, it recognized that it was its duty "to ensure that the law has been correctly applied to the facts." *Id.* at 1343. In other words, the court conducted an independent, de novo review of the legal aspects of the jury's obviousness verdict, deferring only to the jury's presumed factual findings. The court then found the defendant's obviousness case "overwhelming" and reversed the district court's denial of the defendant's motion for JMOL on obviousness. *Id.* at 1344.

- *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982 (Fed. Cir. 2009), *petition for cert. dismissed*, No. 09-103, 2009 U.S. LEXIS 7156 (Oct. 2, 2009). In this case, the Federal Circuit reversed the denial of the alleged infringer's JMOL motion on obviousness, stating that "[w]hen we consider that, even in light of a jury's findings of fact, the references demonstrate an invention to have been obvious, we may reverse its obviousness determination." *Id.* at 990.

In short, it is clear that the Federal Circuit has not just *said* that obviousness is an issue of law. In practice, the court has shown that it is committed to conducting an independent review of jury verdicts concerning obviousness and applying the law to the facts either expressly or implicitly found by the jury.

Moreover, the present case reflects just this type of thorough review. Here, the Federal Circuit conducted a thoughtful, independent review of the

evidence that KCI relied on as supporting the jury's verdict. *See supra* pp. 9-12. Indeed, as part of this process, the Federal Circuit thoroughly examined whether the prior art taught "treating a wound with negative pressure," looking at each of the prior-art techniques Medela relied on. *See supra* p. 11.

In sum, the procedure the Federal Circuit followed here in presuming that the jury's factual findings were in KCI's favor was not a consequence of an abdication of its (or the district court's) role in determining the law. It was the procedure this Court's precedent *required* the Federal Circuit to follow under the circumstances of the case. *See, e.g.*, *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000) (stating that in considering JMOL motions, "the court must draw all reasonable inferences in favor of the nonmoving party"). Medela could have avoided the need to have the Federal Circuit presume the jury's factual findings simply by asking for special interrogatories on the facts underlying the obviousness issue, as the Federal Circuit has expressly encouraged.

C. The Federal Circuit Recognized the Proper Roles of the Jury (Finding the Facts) and the Court (Determining the Law)

1. The "Circuit Split" Is, At Most, Wholly Theoretical

In alleging a "circuit split" on the jury's role in determining obviousness (Pet. 11-17), Medela relies

on two en banc decisions of other circuits that were decided before the Federal Circuit was established to provide nationwide uniformity in patent law. *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) ("Congress conferred exclusive jurisdiction of all patent appeals on the Court of Appeals for the Federal Circuit, in order to 'provide nationwide uniformity in patent law.'"). But neither of the cases Medela relies on conflicts in any *relevant* way with the Federal Circuit's decision below.

Medela's first "circuit split" case is *Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647 (9th Cir. 1982) (en banc) (per curiam). Pet. 11-12. There is no question that, as Medela asserts (*id.* at 11), one aspect of *Sarkisian*—that the jury's role in determining obviousness should be limited to providing (at most) a "nonbinding advisory opinion" (688 F.2d at 651)—has been rejected by the Federal Circuit. *See Perkin-Elmer*, 732 F.2d at 895 n.5. But this difference between the approaches of the two circuits is of absolutely no importance here, and should not affect the decision whether to grant certiorari, since in this case, Medela never asked for an advisory verdict or objected in any way to the issue of obviousness being given to the jury without restrictions. *See supra* pp. 7-8. Indeed, in the Federal Circuit, Medela admitted that it was *not* erroneous to submit the ultimate question of obviousness to the jury. Medela CAFC Reply Br. 3-4 (stating that whether the obviousness question was properly given to the jury was "not the error that

Medela raises," and that the claimed error was that "the District Court erred in failing to engage in any obviousness analysis following the jury's verdict"); App. 19a ("Defendants do not argue that submitting the question of obviousness to the jury is error.").

Further, Medela is wrong in asserting that in *Perkin-Elmer*, the Federal Circuit "rejected the Ninth Circuit's view that the courts must determine nonobviousness independently of the jury's verdict." Pet. 11 (internal quotation marks omitted). On the contrary, the *Perkin-Elmer* court recognized that courts should determine obviousness "independently" of the jury, but held that this did not mean that the jury's verdict could be ignored. In affirming the district court's denial of the alleged infringer's JNOV motion, the Federal Circuit said the following:

> The [trial] court did not, however, appear to interpret the indication in [*Sarkisian*] that it should determine nonobviousness "independently" of the jury's verdict as requiring it to totally ignore the rules applicable to jury trials in non-patent cases, or to proceed as though the jury had never been impanelled, had never been instructed on the issue, had never considered the issue, and had never rendered a verdict on its conclusion.

Perkin-Elmer, 732 F.2d at 895. Thus, the Federal Circuit noted that the trial court had "proceeded in a

manner similar to that involved in deciding a motion JNOV and used the jury's presumed findings supported by substantial evidence." *Id.* And the Federal Circuit concluded that the trial court had "in fact answer[ed] the appropriate question: can the jury's presumed findings support [the] conclusion of nonobviousness encompassed in the jury's verdict of validity?" *Id.*

In sum, in *Perkin-Elmer* (as well as in this case), the Federal Circuit viewed the ultimate issue of obviousness as a legal conclusion (as all courts have), and it also recognized its obligation (as all courts have) to give effect to the jury's factual findings. The Federal Circuit in *Perkin-Elmer* differed with the Ninth Circuit in *Sarkisian* on the question of whether the jury should ever render anything more than a purely advisory verdict on the ultimate issue of obviousness, but that difference has no relevance here, since Medela *consented* to the jury rendering the obviousness verdict.

Medela's second "circuit split" case is *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324 (7th Cir. 1983) (en banc). Pet. 13-14. Medela argues that *Roberts* rejected the Federal Circuit's approach of "requiring a court to hypothesize" the jury's factual findings (*id.* at 13), but what the Seventh Circuit objected to in *Roberts*—where the alleged infringer *had* objected to giving the obviousness issue to the jury (723 F.2d at 1339)—was *not* the need to presume the jury's factual findings from its verdict, but the cursory nature of the instructions the jury

had been given. As the *Roberts* court pointed out, the instructions given there "merely identified the *Graham* underlying factual inquiries and instructed the jury to 'consider the evidence' presented by the parties with respect to them." *Id.* Under those circumstances, the court recognized that the jury was being asked, improperly, to "be the final arbiter of the legal issue of patent validity." *Id.* at 1343.

Indeed, the *Roberts* decision repeatedly emphasized that it is the court's role to determine the law and the jury's role to determine the facts. *See, e.g., id.* at 1341 ("[Q]uestions of law are for the court and questions of fact are for the jury."); *id.* at 1343 ("We do not intend as a court to make a jury's factual decisions."). The court thus held that as long as the court's and jury's separate roles are recognized through proper instructions, asking the jury to return a general verdict on obviousness is perfectly appropriate, since the court can then *presume* that the jury resolved disputed factual matters in the prevailing party's favor. *Id.* at 1341 ("On appeal [from a general verdict on obviousness], the reviewing court will presume that 'the disputed matters of fact have been resolved favorably to the prevailing party in accordance with the trial judge's instructions.'" (quoting *Panther Pumps & Equip. Co. v. Hydrocraft, Inc.*, 468 F.2d 225, 228 (7th Cir. 1972))). The problem the court had in *Roberts*, therefore, was not that it objected to the concept of having to presume the jury's factual findings, but that the trial court's cursory instructions "preclude[d it] from confidently presuming that [the] factual

disputes [underlying obviousness] were resolved in favor of Roberts." *Roberts*, 723 F.2d at 1343.

Moreover, in recognizing the jury's role to find the facts and the court's role to determine the law, the *Roberts* court expressly described the court's role as being to conduct an "independent" review of the obviousness issue. It is just that the *Roberts* court recognized (as the Federal Circuit did in this case) that its role, while independent, was circumscribed by the fact-law distinction and the Federal Rules of Civil Procedure:

> When made in a bench trial, the *Graham* factual determinations are reviewed under the clearly erroneous standard of Rule 52(a), Federal Rules of Civil Procedure. When these factual determinations have been made by a jury, our review is limited, assuming the instructions are not an issue, to ascertaining whether the denial of a motion for a new trial or a motion for a judgment notwithstanding the verdict was an abuse of discretion. *An appellate court's independent review of the trial judge's conclusion of law is predicated upon the factual determinations made in the district court.*

Roberts, 723 F.2d at 1335 (emphasis added); *see also id.* at 1342 n.24 (noting that in *Control Components, Inc. v. Valtek, Inc.*, 609 F.2d 763 (5th Cir. 1980), the

Fifth Circuit had approved a general verdict on obviousness, stating that "[t]he court of appeals' *independent review* of the record disclosed substantial evidence in support of the jury's presumed findings of fact [on the obviousness issue]" (emphasis added)).

In sum, the Seventh Circuit's approach to obviousness in *Roberts* is fully consistent with the Federal Circuit's approach. As is true of the Federal Circuit, the Seventh Circuit in *Roberts* recognized the role of juries (finding the facts) and courts (determining the law), and approved asking the jury to return a general verdict on obviousness on proper instructions. And to the extent that the Seventh Circuit may have spoken in greater detail regarding the specific instructions that may be required, that difference is irrelevant in the present case since, again, Medela *consented to* the instructions on obviousness that the jury received in this case.

Medela is also incorrect in asserting that *Baumstimler v. Rankin*, 677 F.2d 1061 (5th Cir. 1982), reveals either an "intra-circuit split" in the Fifth Circuit or that the Fifth Circuit "has moved into alignment with the circuits opposing the Federal Circuit position." Pet. 15-16 (quoting *Baumstimler*, 677 F.2d at 1072). In *Baumstimler*, the Fifth Circuit vacated the district court's judgment based on faulty jury instructions concerning the burden of proof for invalidity. 677 F.2d at 1063. Then, the court decided to "offer some comments to facilitate retrial." *Id.* at 1063 n.1.

While highly critical of the verdict form used in that case—which did not even require the jury to make a specific finding of validity (*id.* at 1065, 1071)—the court did not broadly forbid general verdicts in the obviousness context or say that if a general verdict was used, a jury's presumed factual findings should be ignored. To be sure, the *Baumstimler* court expressed a strong preference for special interrogatories (*id.* at 1071-72), but so has the Federal Circuit (*see supra* p. 14). And while the *Baumstimler* court suggested that it would be less tolerant of general verdicts in the future, saying that a "failure to utilize [special interrogatories] in a patent case places a heavy burden of convincing the reviewing court that the trial judge did not abuse his discretion" (677 F.2d at 1071-72), it said nothing about what it would do if the parties voluntarily agreed to submit the issue of obviousness to a jury.

In sum, none of the cases Medela relies on conflicts with the Federal Circuit's decision below *in any relevant way.*

2. The Federal Circuit's Approach Was Consistent with This Court's Precedent

Medela argues that Federal Circuit precedent conflicts with this Court's precedent on obviousness. Pet. 17-19. But Medela's argument is based on the statement in *Graham* that "the ultimate question of patent validity, is one of law" (*id.* at 17 (citing *Graham*, 393 U.S. at 17)), and no one—including the

Federal Circuit—has ever disputed that. *See, e.g.*, *PharmaStem*, 491 F.3d at 1359 ("Obviousness is a legal conclusion that we review de novo."). Further, that this Court's *KSR* decision makes "no mention whatsoever of juries conducting the analysis" (Pet. 17) is wholly irrelevant. *KSR* was determined on summary judgment where no jury was involved. *KSR*, 550 U.S. at 412. In fact, *none* of the Supreme Court case law cited by Medela (Pet. 2-3)[6] involved an appeal following a jury trial. But beyond that, the jury in the present case did not "conduct the analysis" of obviousness in the sense Medela implies. The jury here (following consented-to instructions) *found the facts underlying obviousness* and then reached a verdict on obviousness that, following the district court's instructions, flowed from those facts. And the district court then performed its role (as the Federal Circuit later did on appeal), deciding whether the jury's decision was legally correct while presuming (since it had no other option) that the jury's factual findings were in KCI's favor as the prevailing party.

Finally, Medela's complaint that the instructions on obviousness were deficient because they were only seven pages long, while one casebook

---

[6] *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976) (no reference to jury trial); *Dann v. Johnston*, 425 U.S. 219 (1976) (appeal from ex parte prosecution); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969) (no reference to jury trial); *United States v. Adams*, 383 U.S. 39 (1966) (appeal from Court of Claims).

"devotes over 160 pages to the exposition of obviousness law" and two other legal sources spend, respectively, 25-plus and 40-plus pages on the issue (Pet. 18-19), strains credulity. The *length* of the instructions is not the issue. Medela points to no *error* in the instructions, and in any event, the fact remains that Medela *stipulated* to them. *See supra* pp. 7-8.

D. Medela's Argument that the Jury Should Have *No* Role in Deciding Obviousness Goes Too Far

Medela concludes its brief with an outright attack on the jury having *any* involvement in the determination of obviousness. Pet. 19-30. But this request contradicts a core principle of our judicial system—that it is the jury's province to determine the credibility of trial witnesses and make factual findings, not the court's. Medela's request should be rejected out of hand.

Medela begins its argument by discussing cases that deal with administrative orders and arguing that because the PTO is an administrative agency and a patent is an administrative order, any fact-finding required in determining obviousness should be performed by a judge, not a jury. *Id.* at 19-22. But whether or not certain challenges to administrative orders may—under the particular circumstances of those cases—involve factual issues that a judge resolves is wholly beside the point.

Beginning at least as early as in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851), this Court has approved giving the issue of obviousness to the jury on proper instructions. *Id.* at 267. And in *Graham*, where this Court dictated that there are "basic factual inquiries" underlying the ultimate legal determination of obviousness (*see* 383 U.S. at 17), the clear implication was that if a jury was involved in the case, it would decide the factual issues. Moreover, *every* court that has considered the issue—including Medela's "circuit split" cases, *Sarkisian* and *Roberts*—has concluded that the facts underlying obviousness are to be decided by the jury. *See Sarkisian*, 688 F.2d at 650 (finding that the *Graham* factors are "factual determinations . . . made by the fact finder, preferably by detailed special interrogatories in jury trials"); *Roberts*, 723 F.2d at 1333 ("[W]here material factual disputes exist . . . , issues for jury determination, if a jury is to be the fact-finder, are presented."). Indeed, Medela does not argue otherwise.

Further, the Federal Circuit's treatment of obviousness is consistent with this Court's treatment of other patent-law issues that involve mixed questions of fact and law. In *Tucker v. Spalding*, 80 U.S. (13 Wall.) 453 (1872), for example, this Court held that the question of novelty, being a "mixed question of law and fact," must be given to the jury on proper instructions:

> [T]hough the principles by which the question must be decided may be very

> largely propositions of law, it still remains the essential nature of the jury trial that while the court may on this mixed question of law and fact, lay down to the jury the law which should govern them, so as to guide them to truth, and guard them against error, and may, if they disregard instructions, set aside their verdict, the ultimate response to the question must come from the jury.

Id. at 455. *See also Hogg v. Emerson*, 52 U.S. (11 How.) 587, 607 (1850) (stating that because the question of whether the patent-in-suit's drawings were corrected within a reasonable time was "a point in part of law and in part of fact," the issue "was properly submitted to the jury, and their finding must stand, unless it is shown, as has not been done, that illegal instructions were given to them concerning it, or that proper legal directions were omitted").

The entitlement to having a jury decide mixed questions of fact and law is equally true in areas outside of patent law. *See, e.g., McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 356 (1991) (holding that the question of who is a "seaman" under the Jones Act is "better characterized as a mixed question of law and fact," that "[t]he jury finds the facts and, in these cases, applies the legal standard," and that so long as "reasonable persons, applying the proper legal standard, could differ," the issue of

seaman status "is a question for the jury"); *Manchester v. Ericsson*, 105 U.S. 347, 350 (1881) (holding that the question of whether the city of Manchester had "assumed charge of the place" where an accident occurred "was a mixed question of law and fact, proper for the jury, aided by the court"); *Republican River Bridge Co. v. Kan. Pac. Ry. Co.*, 92 U.S. 315, 318 (1875) (holding that the ownership of real estate "must from its very nature be a mixed question of law and fact, which would be concluded by the verdict of a jury"); *Cooley v. O'Connor*, 79 U.S. (12 Wall.) 391, 400 (1870) ("Whether the demands of the statute respecting notice of sale had been complied with was a mixed question of law and of fact, and it should have been submitted to the jury."); *Chesapeake Ins. Co. v. Stark*, 10 U.S. (6 Cranch) 268, 273 (1810) (holding that the issue of whether an abandonment was made in reasonable time "remains a question, compounded of fact and law, which must be found by a jury, under the direction of the court").

Moreover, while Medela cites an article broadly questioning "the ability of juries to decide complex patent cases rationally" (Pet. 26), that has never been the view of this Court. As is seen from the cases discussed above—including especially *Hotchkiss* (regarding obviousness) and *Tucker* (regarding novelty)—this Court has never hesitated to allow juries in patent cases to resolve issues that are unquestionably complex. *See also Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1877) (holding, on the issue of infringement under the doctrine of

equivalents, that "in determining the question of infringement, the court or jury, as the case may be, . . . are to look at the machines or their several devices or elements in the light of what they do, or what office or function they perform, and how they perform it, and to find that one thing is substantially the same as another, if it performs substantially the same function in substantially the same way to obtain the same result").

Also, patent law is hardly the only area of the law that involves complex issues. And while some courts have recognized the *theoretical* possibility of a complexity exception to the right to a jury trial, to KCI's knowledge, neither this Court nor any court of appeals has ever held that the right to a jury should be abrogated in a given case because of the case's complexity—whether in the context of patent law, securities law, antitrust law, or any other area of the law that may involve difficult issues. In *Davis & Cox v. Summa Corp.*, 751 F.2d 1507 (9th Cir. 1985), for example, the court held that it was error to refuse a jury demand because of the complexity of an issue:

> [T]here is no complexity exception to the Seventh Amendment right to jury trial in civil cases. . . . And we do not believe any case is so overwhelmingly complex that it is beyond the abilities of a jury.

Id. at 1516 (quoting *In re U.S. Fin. Sec. Litig.*, 609 F.2d 411, 432 (9th Cir. 1979)). *See also United*

States v. Torniero, 735 F.2d 725, 734 (2d Cir. 1984) ("The framers of the Bill of Rights expected that juries would be capable of resolving disputed issues of fact in the federal courts. Even in civil litigation, where non-perspicuous issues and abstruse evidence proliferate, we have never acknowledged a 'complexity exception' to the right to a jury trial.") (citation omitted); *In re Japanese Elec. Prods. Antitrust Litig.*, 631 F.2d 1069, 1088 (3d Cir. 1980) (recognizing the theoretical possibility that a suit may be so complex that trial by jury might be denied, but holding that "[t]he complexity of a suit must be so great that it renders the suit beyond the ability of a jury to decide by rational means").

Similarly irrelevant is Medela's complaint (based on the same article) that juries have been used in patent cases more frequently in recent years than in the past (Pet. 26). The preference of some parties—whether patentees or alleged infringers, and whether for or against juries—is simply irrelevant to the determination of the proper *constitutional* role of the jury in patent cases.

Medela also cites this Court's grant of certiorari in *American Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995), as allegedly "the best gauge of importance" to the issue presented in this case. Pet. 23. But the question in *American Airlines* was whether there was a right to a jury trial in a declaratory-judgment action where the claimant did not seek legal relief. That question is hardly similar to the question of the jury's proper role in the

determination of an issue, such as obviousness, that is admitted to be a legal issue with underlying factual issues. Moreover, while Medela quotes Judge Nies's dissent from the denial of rehearing en banc in *Lockwood* (Pet. 23), she would not have sympathized with Medela in this case. Despite her dislike of "black box" jury verdicts, Judge Nies also stated that "[i]f both parties agree to that procedure, so be it." *In re Lockwood*, 50 F.3d 966, 990 (Fed. Cir. 1995) (Nies, J., dissenting).

In fact, while Medela ignores the effect of its consent to the procedures followed in the district court, it is hard to contemplate why Medela should be excused from the consequences of its decision. If the jury had found for Medela on the obviousness issue, Medela would have been perfectly content with the verdict and would never have argued that the court was required to ignore the verdict and decide obviousness on its own. In short, there is no reason for this Court to consider Medela's after-the-fact complaints about a procedure that it fully consented to at the time.

CONCLUSION

For the foregoing reasons, Medela's petition for a writ of certiorari should be denied.

Respectfully Submitted,

R. Laurence Macon
Karen Kroesche Gulde
Akin Gump Strauss
Hauer & Feld LLP
300 Convent Street
San Antonio, TX 78205
(210) 281-7000

Of Counsel

Donald R. Dunner
Counsel of Record
Don O. Burley
Erik R. Puknys
Tina E. Hulse
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4000

Attorneys for Respondents Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Life Sciences